

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
)		MDL No. 2419
)		Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO:)	
)		
All Cases)	
)		

**TENNESSEE CLINIC DEFENDANTS¹ MOTION FOR CLARIFICATION RE:
DEPOSITIONS OF THE FDA AND WITNESSES FROM THE NECC CRIMINAL CASE**

The Court previously entered orders temporarily staying the depositions of witnesses in the NECC criminal case. With the conclusion of Barry Cadden's criminal trial, the Tennessee Clinic Defendants now need to proceed with these depositions. However, the prospective deponents and Government still oppose the depositions taking place. Left with no choice but to seek the Court's guidance, the Tennessee Clinic Defendants move to clarify whether the depositions of the FDA,² Joe Connolly, John Notarianni, Rob Ronzio, and Barry Cadden can now go forward.

To decide this, the Court need only apply the previous orders to answer three simple questions:

1. Connolly and Notarianni: Has "the first criminal trial at which they testify" concluded so that the Tennessee Clinic Defendants can now depose them?
2. FDA: Is the end of the Cadden criminal trial a "resolution of the criminal case" so that the Tennessee Clinic Defendants can now depose the FDA?
3. Cadden and Ronzio: Have the criminal charges "resolved" so that the Tennessee Clinic Defendants can now depose them?

¹ Specialty Surgery Center, PLLC, Kenneth Lister, MD, PC, Kenneth Lister, MD, and Donald Jones, MD.

² The Tennessee Clinic Defendants seek testimony of a Fed. R. Civ. P. 30(b)(6) representative of the FDA on the topics set forth in their original subpoena and deposition notice at Doc. 1720.

Background

Attempts to Depose the FDA and NECC Witnesses

In early 2015, clinic defendants in the MDL issued deposition subpoenas to the FDA, NECC criminal defendants, and unindicted former employees of NECC and its affiliated companies. The clinic defendants sought the testimony to further the defense of the cases against them. In response, the deponents moved for protective orders precluding the depositions.³ The Court (1) stayed the FDA deposition “until resolution of the criminal case,” (2) stayed the criminal defendants’ depositions “pending resolution of the criminal charges against them,” but (3) allowed the depositions of unindicted former employees of NECC and its related companies to proceed.⁴

The Government then intervened in the civil case and asked the Court to stay depositions of the third category of witnesses (unindicted former employees of NECC or Medical Sales Management (“MSM”)).⁵ The Court refused to grant a blanket stay of the depositions but permitted the Government to file a more specific motion.⁶ The Government then filed an *ex parte* motion under seal asking the Court to stay the depositions of Joe Connolly, a former employee of NECC, and John Notarianni, a former sales employee of MSM.⁷ The Court granted the Government’s *ex parte* motion and stayed the depositions until “the conclusion of the first criminal trial at which they testify or further order of the Court.”⁸

³ Docs. 1823, 1836, 1838.

⁴ Doc. 2123 at 15-22.

⁵ Doc. 2209.

⁶ Doc. 2354 at 3.

⁷ Doc. 2520.

⁸ Doc. 2556.

Cadden Criminal Trial Testimony

Rob Ronzio (director of NECC/MSM sales) was indicted and pled guilty. He subsequently testified in the criminal trial against Barry Cadden. Joe Connolly was not indicted and testified at the Cadden trial. John Notarianni was not indicted and did *not* testify at the Cadden trial. Several FDA investigators testified at Cadden's trial.

On March 22, 2017, Cadden's trial concluded, with acquittals on some charges and convictions on others.

Summary of Argument

A district court speaks to the parties through its orders.⁹ The words the district court uses in the order are important.¹⁰ When a court's order is clear, a party cannot disregard its plain language "in an effort to suit interpretive convenience."¹¹ Unless the order is amended or vacated, the district court should enforce it.¹²

The protective orders staying the depositions of the FDA, Joe Connolly, John Notarianni, Barry Cadden, and Rob Ronzio were clear. They were temporary stays, in effect until the conclusion of the criminal case. Now that the Cadden criminal trial is complete, and with trials against clinics fast approaching, the time has come to proceed with these depositions, as the prior orders clearly intended.

Further, if the Court looks beyond the simple, plain language of the previous orders, the justifications for staying these depositions are largely, if not completely, wiped out at this juncture.

⁹ *Negron-Almeda v. Santiago*, 528 F.3d 15, 22-23 (1st Cir. 2008).

¹⁰ *Id.* at 23.

¹¹ *Id.* (additional cites omitted).

¹² *Id.*

Law and Argument

I. The Court's previous ruling allows the Tennessee Clinic Defendants to now depose Joe Connolly.

a. Joe Connolly has important, relevant testimony that the Tennessee Clinic Defendants need for trial.

Joe Connolly is the only pharmacy technician from NECC willing to testify substantively in the civil cases. Every other technician who was deposed pled the Fifth in response to substantive questioning. Thus, Connolly's testimony can (and will) be used to explain to juries in trials against clinics across the country how NECC operated the cleanroom where the MPA was contaminated.¹³

In the Cadden criminal trial, Connolly testified that:

- The contaminated MPA was compounded by Glenn Chin, Cory Fletcher, and Owen Finnegan in Hoods 1 and 2 in Cleanroom 1.
- Chin supervised Cleanroom 1 but would either deflect, ignore, or shrug off concerns raised by the technicians.
- In the spring of 2012, Connolly told Chin that increased production at NECC was going to lead to mistakes in the compounding process, and Chin shrugged his shoulders in response.
- NECC labeled medications with incorrect lot numbers so they would appear to be from lots that were tested for sterility and endotoxins, when they had not actually been tested.

Connolly's testimony is critical for the Tennessee Clinic Defendants to prove that (1) the fault for these events begins and ends with NECC¹⁴ and (2) NECC's actions

¹³ See Deposition Protocol, permitting depositions to be cross-noticed in cases other jurisdictions related to NECC. Doc. 1426 at 8.

¹⁴ As this Court knows by now, Tennessee is a modified comparative fault state. See *McIntyre v. Valentine*, 833 S.W.2d 52, 56-58 (Tenn. 1992). Thus, at trial, the Tennessee Clinic Defendants will be responsible for proving the fault of NECC, a non-party, and the jury will be instructed to allocate a portion of fault to NECC.

constitute a superseding and intervening cause absolving the clinics of liability¹⁵. The testimony is unquestionably relevant to defenses in the case.¹⁶ Without him, the Tennessee Clinic Defendants lack a firsthand description of NECC's manufacturing process, and the problems with it.

Importantly, much of Connolly's testimony cannot be established by the documents produced in the civil cases. For example, he testified that NECC falsified documentation, demonstrating the documents themselves are unreliable. Even where some reliable documentary evidence does exist, it is not an adequate substitute for much more persuasive live testimony. (Indeed, the Government apparently agrees that documents are insufficient, calling more than 50 live witnesses during its case-in-chief against Cadden.)

Connolly has relevant, important information for the defense of the cases, information he is willing to offer in a deposition.

b. The plain language of the Court's order staying Connolly's deposition permits the deposition now that he has testified at Cadden's trial.

The Court's directive on Connolly's deposition was clear: The deposition was stayed "until the conclusion of the first criminal trial at which [he] testif[ies]."¹⁷ The Government has not moved to modify the order. With Cadden's trial now complete and Connolly having testified, the condition precedent for expiration of the stay has occurred. The deposition can and should proceed.

¹⁵ In Tennessee, superseding intervening cause is an affirmative defense to a negligence claim. See *Howell v. Turner*, No. M2008-01588-COA-R3-CV, 2009 WL 1422982, *4 (Tenn. Ct. App. 2009); *Godbee v. Dimick*, 213 S.W.3d 865, 883 (Tenn. Ct. App. 2006). The defendant is responsible for proving it.

¹⁶ FED. R. CIV. P. 26.

¹⁷ Doc. 2556.

II. The Court’s previous ruling allows Tennessee Clinic Defendants to depose the FDA.

a. The FDA has important, relevant information that needs to be explored in deposition testimony to prepare for and use at trial.

The FDA’s involvement with NECC spanned ten eventful years. The FDA inspected NECC twice in 2002; issued a warning letter and several deficiency reports; communicated with state authorities about NECC; fielded complaints about NECC in 2007, 2008, 2009, and 2010; was supposed to do another inspection 2008 but failed to do so; and received complaints about NECC’s problems in 2011. Thus, while the level of regulatory authority over NECC may be disputed, there is *no* dispute that the FDA exercised *some* regulatory oversight of NECC.

The Tennessee Clinic Defendants need to depose the FDA for three straightforward reasons:

First, a primary factual defense to the claim of “negligent purchasing” is that the clinic defendants reasonably assumed the FDA was regulating all drug-makers in the United States. To present that defense effectively to the jury, the clinic defendants must develop proof that the FDA regulated drug-makers like NECC. The clinic defendants need to establish in a deposition that the FDA had regulatory authority, exercised that authority, and expected health care providers to rely on it to keep drug-makers in line.

Second, the clinic defendants assert the fault of the FDA as an affirmative defense, and the Court ruled that this defense may proceed.¹⁸ Testimony from the FDA is necessary to develop and prove the defense. The clinic defendants cannot seriously be

¹⁸ Doc. 3377.

expected to carry their burden of proving the FDA acted recklessly without testimony from the FDA.

Third, the clinic defendants will also defend the cases by proving the fault of NECC. At Cadden's trial, the FDA agents testified that NECC was not properly sterilizing medication in 2002, just as it failed to properly sterilize the MPA responsible for the fungal meningitis outbreak in 2012, and that NECC was not conducting required end-product testing in 2002, just as it failed to do with the MPA at issue in 2012. Facts like these establish NECC's fault and help prove the clinic defendants' comparative fault defense.

The FDA will likely argue that the clinic defendants should be satisfied with the FDA's document production in the civil case, and forego testimony. However, as with Connolly, the Government apparently was unsatisfied with documentary evidence alone, and presented testimony from seven different FDA employees at Cadden's trial. The clinic defendants likewise should not be forced to present their case through documents alone.

The FDA's testimony is not only relevant, it is essential to the Tennessee Clinic Defendants' defense of the case.

b. The Court's prior order permits the Tennessee Clinic Defendants to now proceed with the FDA's deposition.

The first time around, the FDA argued "that it should not be subject to a deposition during the pendency of the Cadden criminal case."¹⁹ The Court agreed and temporarily stayed the deposition of the FDA: "[T]he Court finds that a protective order precluding the FDA's deposition *until the resolution of the criminal case* is appropriate under the circumstances."²⁰

¹⁹ Doc. 2123 at 12.

²⁰ Doc. 2123 at 21 (emphasis added).

At the time of the Court's order, none of the criminal defendants had been severed from the Cadden case. The FDA and the clinic defendants disagree as to whether the conclusion of Barry Cadden's trial constitutes "resolution" of the criminal case. The clinic defendants respectfully submit that it does.

Indeed, the Court's subsequent order staying Connolly and Notarianni's deposition until the conclusion of the first criminal trial at which they testified, indicates that the Court intended for the depositions of criminal trial witnesses to proceed once their testimony was disclosed in the criminal proceeding. That has now occurred with respect to the FDA. At Cadden's trial, multiple FDA agents testified about virtually every aspect of NECC's interactions with the FDA.

To the extent the Court determines that its prior order requires more than just clarification on this point, it may consider this a motion to revise the order to permit the deposition now that the FDA testified at Cadden's trial. As explained in the next section, there is no longer any legitimate basis for prohibiting the deposition of the FDA.

III. The reasons for staying the depositions of the FDA and Connolly are no longer present.

In addition to the language of the orders, the prior justifications for imposing the stay no longer support its continued existence. In their original briefing²¹, the Government and FDA argued that, because of the overlap between the civil and criminal cases, the depositions of Connolly and the FDA would potentially impede the criminal prosecution by (1) prematurely disclosing elements of the Government's case against Cadden, (2) generating publicity that could affect the right to a fair trial, and (3) requiring the

²¹ In addition to the materials in the public record, the Government filed an *ex parte* motion. The Tennessee Clinic Defendants do not know its contents.

Government to prepare witnesses to ensure their testimony was consistent with the anticipated criminal trial testimony.²²

These concerns no longer exist. The Government has presented its case against Cadden, eliminating any concern about publicity or revealing testimony or trial strategy. Moreover, the Government already prepped these witnesses to testify at Cadden's trial; so additional prep should be minimal. With respect to the FDA, one (or more) of the seven agents who testified about the FDA's history with NECC at the Cadden trial can serve as the FDA's 30(b)(6) representative in a deposition with minimal additional prep, limiting any burden on the prosecution team or the FDA.

The only remaining concern is that the deposition testimony *might* serve as impeachment material *if* it is inconsistent with other testimony given by the witnesses. However, this concern should be minimal as long as the witnesses testify truthfully, and certainly does not, by itself, satisfy the "heavy burden" of continuing the stay of the civil cases.²³

The arguments that these depositions will interfere with the criminal process by "tipping the prosecution's hand" or overburdening the Government with additional preparation just are not present now that Cadden's trial is over.

²² See Affidavit of U.S. Attorney Carmen Ortiz at Doc. 1838-3.

²³ *Microfinancial, Inc. v. Premier Holidays Intern.*, 385 F. 3d 72, 77 (1st Cir. 2004).

IV. The clinic defendants should be permitted to depose Notarianni because the Government did not even call him to testify at Cadden's criminal trial.

a. Notarianni has relevant, important information for the clinic defendants' defense of these cases.

Similar to Connolly, John Notarianni is the only former salesperson who has agreed to testify substantively in the MDL. Assuming Notarianni's testimony is consistent with the salespeople who testified at the Cadden trial (pursuant to immunity/cooperation agreements), Notarianni will likely testify that NECC's business model was built on (1) salespeople telling health care providers that NECC's products were superior and (2) providers relying on those representations in purchasing the medications.

This testimony is critical to the cases against clinics, who relied almost entirely on the representations of NECC's salesforce about the products' safety in deciding to buy from NECC. The crux of the cases against the clinic defendants is whether they reasonably relied upon these representations, or should have done further due diligence before buying. Jurors must be able to hear the testimony of at least one salesman to decide whether the critical purchase decision was reasonable.

Notarianni has relevant, important information for the clinic defendants' defense of the cases, and should be permitted to sit for a deposition.

b. The Court's prior order should not preclude the Tennessee Clinic Defendants from deposing Notarianni.

As with Connolly, the Court stayed the deposition of John Notarianni until the conclusion of the first criminal trial at which he testified. However, Notarianni did not testify at the Cadden trial. The Government presumably decided that his testimony was unnecessary for the criminal trial. Thus, there is no reason for Notarianni's deposition to remain stayed. Procedurally, the Court can consider this a motion to revise the previous

order to allow the deposition of Notarianni, or the Court can clarify its previous order to state that Notarianni can be deposed because he was not called in the criminal case. Either way, the deposition of Notarianni should proceed.

V. The Court should permit the depositions of Cadden and Ronzio as the criminal charges against them “resolved” when Ronzio pled guilty and Cadden’s trial concluded.²⁴

The Tennessee Clinic Defendants also seek clarification of the prior order staying the depositions of criminal defendants (like Ronzio and Cadden) “pending resolution of the criminal charges against them.”²⁵ The criminal charges have now resolved for both Ronzio and Cadden to the point that a civil deposition will not meaningfully interfere with the criminal process.

As the Court noted in its protective order, the clinic defendants would generally be allowed to take these depositions, with Cadden and Ronzio invoking their Fifth Amendment right against self-incrimination on a question-by-question basis.²⁶ ²⁷ The clinic defendants could then use this testimony to persuade the jury to draw an adverse inference regarding Cadden and Ronzio’s role in the outbreak.²⁸ Or, there may be certain questions not reasonably likely to lead to incrimination, that the witness may choose to (or be ordered to) answer.²⁹

The Eighth Circuit has observed that allowing parties to play videotaped testimony of a nonparty invoking the Fifth Amendment helps explain to the jury why the party bearing

²⁴ At this point, the clinic defendants do not seek depositions of criminal defendants who have not been tried or pled guilty.

²⁵ Doc. 2123 at 16.

²⁶ Doc. 2123 at 15-16.

²⁷ Cadden and Ronzio, through their attorneys, indicate they intend to take the Fifth if deposed, even now.

²⁸ *Baxter v. Palmigiano*, 425 U.S. 308, 318 (1976).

²⁹ *Hoffman v. U.S.*, 341 U.S. 479, 487 (1951) (holding that a court may require a witness to answer questions where “it clearly appears to the court that he is mistaken” that the answer may incriminate him).

the burden of proof had to resort to less direct forms of evidence.³⁰ “Otherwise, the jury might have inferred the [clinic defendants] did not call [the witness] because his testimony would have damaged their case.”³¹ That exact circumstance is present here. Much of the defense to the claims against the clinic defendants is the malfeasance of NECC. Without testimony from Cadden and other upper-level NECC employees, the jury will be left to wonder why the clinic defendants chose to present their defense through documentation rather than testimony.

Cadden’s position (discussed during the meet and confer) is that the criminal charges are not “resolved” because (1) he has not been sentenced, (2) the court has not ruled on his motion for judgment of acquittal or for a new trial, and (3) he has not exercised any of his appellate rights. Ronzio’s position is that the criminal charges against him are not “resolved” because Judge Stearns deferred acceptance of his guilty plea.

Neither argument warrants indefinitely staying the depositions. Cadden and Ronzio are no longer facing a criminal trial – Cadden by virtue of his conviction and Ronzio by virtue of his guilty plea. Thus, the Court’s concern about the “substantial overlap” between the subject matter of the two trials is no longer at issue.³² Indeed, the criminal defendants’ initial motion for protective order specifically cited the fact that the civil trials were scheduled to occur before the criminal trials as one of the bases for a stay.³³

³⁰ *Cerro Gordo Charity v. Fireman’s Fund Am. Life Ins. Co.*, 819 F.2d 1471, 1482 (8th Cir. 1987).

³¹ *Id.*

³² See *S.E.C. v. O’Neill*, 98 F. Supp. 3d 219, 224 (D. Mass. 2015) (denying motion for stay of civil proceeding where defendant already pled guilty in parallel criminal proceeding); see generally *S.E.C. v. TelexFree, Inc.*, 52 F. Supp. 3d 349, 353 (D. Mass. 2014) (noting that staying a civil case is appropriate until conviction or plea bargain in the criminal case).

³³ Doc. 1823 at 9 (“The risk is particularly great for Invoking Defendants because the civil trials at which these depositions would be used will, based on current scheduling, precede the Invoking Defendants’ criminal trials. The prejudice to such a public display is obvious and is unnecessary.” (emphasis in original)).

Moreover, it may be years before the criminal charges against Cadden and Ronzio are “resolved” under their definition of the term. Cadden’s appeals will likely extend for some time, and Ronzio, a cooperating witness, may not be sentenced until he has completed his cooperation by testifying in the criminal trials of the remaining eight criminal defendants.

In short, circumstances have changed. Cadden and Ronzio can no longer establish good cause for continuing the stay of their depositions because the criminal charges have resolved.

VI. The criminal trial transcripts are an inadequate substitute for deposition testimony in the civil cases.

The Government and witnesses who testified in the criminal case (FDA, Connolly, and Ronzio) will likely argue that the criminal trial transcripts obviate the need for depositions in the civil case. First, this overlooks the fact that the orders in place allow these depositions now that the criminal case has concluded. Nevertheless, this argument ignores a critical evidentiary issue – the criminal trial testimony is inadmissible hearsay in the civil cases, while deposition testimony can be used at trial if the witness is unavailable.³⁴ During the meet and confer process, counsel for the Government and deponents argued that the hearsay exception for former testimony in Fed. R. Evid. 804(b) applies. However, the exception requires examination (or cross-examination) of the witness by a party with similar motives, not present here.³⁵

³⁴ For example, at least some of these witnesses will be outside the subpoena power of the U.S. District Court for the Eastern District of Tennessee, to which the case against Donald Jones, MD is being remanded.

³⁵ FED. R. EVID. 804(b)(1)(B).

With regard to the FDA, neither the Government nor Cadden shared the clinic defendants' motive to establish that the FDA contributed to cause the plaintiffs' alleged injuries in failing to step in and take appropriate action to prevent the outbreak. Likewise, neither had any interest in establishing what information about NECC from the FDA was publicly available for potential customers, a key issue given the allegation that the clinic defendants should have contacted the FDA about NECC prior to purchasing.³⁶

With respect to Connolly and Ronzio, the clinic defendants anticipate that the plaintiffs in individual cases will argue that no party at the Cadden trial questioned Connolly or Ronzio with the goal of establishing that the blame for the outbreak rests with the clinic defendants. Thus, the hearsay exception (arguably) does not apply. If the Court agrees with the plaintiffs, the clinic defendants will be left with no testimony from these important witnesses.³⁷

On the other hand, if the Court allows the depositions to proceed, the Deposition Protocol permits the depositions to be cross-noticed in any case related to the outbreak, thereby allowing a single deposition to be used in any number of the cases across the country currently pending against clinics.^{38 39} This serves the MDL's purpose of providing a reasonable and efficient solution to a difficult problem, particularly now that the first criminal trial is complete.

³⁶ 2nd Am. Master Compl., Doc 1719 at ¶ 234 ("The Clinic Related Defendants failed to investigate NECC's regulatory history with the FDA....").

³⁷ Addressing this argument in no way concedes that a transcript from the criminal case, read to the jury in the civil case, is an equivalent substitute for live testimony from the witness. It most certainly is not.

³⁸ Doc. 1426 at 8.

³⁹ Even if the plaintiffs in the MDL agree to stipulate to the admissibility of the testimony, the stipulation will not bind plaintiffs with cases in other jurisdictions. A deposition cross-noticed in that case will apply to the case.

Conclusion

Prior to Cadden's criminal trial, the balance of the interests between the criminal and civil cases was a close one. The Court chose to protect the criminal process, at the expense of the civil defendants' ability to take the depositions of witnesses with relevant information necessary to develop defenses. The clear language of the prior orders now allows these depositions to be taken.

Indeed, Cadden's criminal trial is now over, and the relevant witnesses have testified. The balance weighs heavily in favor of now permitting the depositions of the FDA, Connolly, Notarianni, Cadden, and Ronzio. The justifications for staying the depositions are either reduced or eliminated entirely, but the critical need for the depositions in the civil cases remains. Requiring these witnesses to sit for a single civil deposition is an appropriate balancing of the interests at play. The Court should stick to the order in place and clarify it to the extent needed, allowing these depositions to proceed.⁴⁰

⁴⁰ While mediation for the SSC cases is currently scheduled in June, the common fact discovery deadline in those cases is August 1, 2017. The SSC Defendants acknowledge the Court's statement in the most recent scheduling order that "The parties should not anticipate any further extensions of the discovery deadlines." Doc. 3359. Accordingly, the defendants attempted to file this motion with adequate time for a decision and (if granted) depositions, prior to the August 1 deadline.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies are being emailed to the individuals identified below this 18th day of May, 2017.

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